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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,878	11/17/2000	Patrick Rivelli JR.	5877-0011.30	7631

490 7590 02/08/2005

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/715,878		RIVELLI, PATRICK	
	<b>Examiner</b>		<b>Art Unit</b>	
	(Jackie) Tan-Uyen T. Ho		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/04 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "such that the distance between adjacent sides of the wave at points between the point intermediate opposite peaks and each of the opposite peaks is greater than that of the point intermediate opposite peaks" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed had possession of the claimed invention.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner is unclear whether each of the wave segments as claimed, including three peaks or two peaks and a wave; a wave segment is the same or a wave segment is a segment of a wave; where does a wave start and end and what are the adjacent sides of a wave. The claim language "each segment containing a pair of opposite looped peaks and having a wave shape .....the distance between adjacent sides of a wave ..... a wave is a minimum at a point intermediate opposite peaks" makes it unclear what subject matter being claimed.
6. Examiner makes an art rejection base on her best understand of the claim invention as follow.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. (6,053,941) in view of Lauterjung (5,630,829). Lindenberg et al. disclose a stent including :

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- A plurality of expandable tubular members (2, 2a, 2b, 2c), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (3, 3a, 3b, 3c), wherein the wire element are formed of a NiTi shape memory alloy wherein the shape memory alloy has a stress-induced martensite phase at body temperature (inherent) and austenite phase transition temperature below body temperature (col. 3, lines 30-65),
- Axial connectors (4 to 4d) joining one or more confronting peaks of adjacent tubular member, wherein the axial connectors are spaced from one another by intervening, unconnected confronting peaks (figs. 1 and 2, col. 2, line 48 to col. 3, line 29), wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one other, without significant change in the axial dimension of the stent.

Although, Lindenberg et al. do not disclose the each segment having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks, attention is directed to the Lauterjung reference which teaches a stent including:

- A plurality of expandable tubular members (figs. 1 and 5), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (16, 18) and having a

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wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks (16, 18), increases monotonically with an inflection point (20) there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks (col. 5, lines 36-67 and col. 6, lines 18-51),

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Lindenberg et al. stent having segments, each having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks. Doing so would provide a stent in its contracted state having circumferential at a minimum in order to be loaded into a small intravascular catheter for delivering and implantation within a small vessel.

9. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. '941 in view of Lauterjung '388 further in view of Pinchasik et al. (5,449,373). The teaching of Lindenberg et al. in view of Lauterjung (see paragraph 8 above) fails to disclose a stent in its contracted state has inner diameter of between .5 and 2 mm and in its expanded state is between 2-9 times that in its contracted state. Pinchasik et al. reference which disclose a stent for delivering through a curved bodily conduit having constricted and expanded diameters typically fall in the ranges of 1.0-3.5

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mm and 3.5-10.0 mm, respectively (col. 3, line 65 to col. 4, line 8). It's also known in the art that human blood vessels typically range from 2mm to 8 mm or may be more or less depending on an individual.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stent of Lindenberg et al. in view of Lauterjung having a diameter of between 1-3.5 mm in its contracted state and in its expanded state is between 2-9 times than in its contracted state in order to be easily advanced through vessels having less than 8 mm in diameter as well as to dilate and support the vessels.

10. Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. '941 in view of Lauterjung '388 further in view of Pinchasik et al. '373 further in view of Ritchart et al. (4,994,069). The teaching of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. discloses the stent as claimed (see paragraphs above).

Although, the teaching of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. fails to disclose a delivery system and method for delivering the stent into a target vessel having inner diameter less than about 8 mm, attention is directed to the Ritchart et al. reference which disclose treating a method for placing a shape memory implant into a selected vessel by using delivery system designed for accessing small vessel, .05 to 6mm in diameter (col. 3, lines 21-35, col. 6, lines 39-67) wherein the system including a catheter (12) having inner diameter about 40-80% larger than the diameter of the implant (col. 6, lines 39-67), a guide wire for guiding the catheter to the

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selected vessel and being removed as the catheter reaching the selected site (col. 8, lines 22-38) and the guidewire being replaced with a pusher (16) for pushing the implant out of the catheter (12) into the selected site.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Ritchart et al. to employ the delivery system and method designed for accessing small vessel, .05 to 6mm in diameter for delivering the stent of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. in order to deliver and deploy the stent to a target site via a tortuous vessel path that has .05 to 6mm or less than 8 mm in diameter.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

February 2, 2005